

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 17-1996V

Filed: July 12, 2019

UNPUBLISHED

MARYLOU PORZIO,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Special Processing Unit (SPU);
Findings of Fact Regarding Route of
Vaccination; Influenza (Flu) Vaccine;
Shoulder Injury Related to Vaccine
Administration (SIRVA)

Leah VaSahnja Durant, Law Offices of Leah V. Durant, PLLC, Washington, DC, for petitioner.

Camille Michelle Collett, U.S. Department of Justice, Washington, DC, for respondent.

FACT RULING and SCHEDULING ORDER¹

Dorsey, Chief Special Master:

On December 21, 2017, petitioner filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*,² (the “Vaccine Act”). Petitioner alleges that she suffered a Shoulder Injury Related to Vaccine Administration (“SIRVA”) as a result of receiving an influenza (“flu”) vaccination on January 5, 2017. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

¹ The undersigned intends to post this decision on the United States Court of Federal Claims' website. **This means the decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access. Because this unpublished decision contains a reasoned explanation for the action in this case, undersigned is required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services).

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all “§” references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

On November 19, 2018, petitioner filed a status report stating that the parties could explore informal resolution of this case if petitioner was able to produce additional evidence that the vaccine was administered intramuscularly. ECF No. 23. Petitioner was directed to submit additional evidence by April 15, 2019, and that the undersigned would issue a fact ruling as to the route of administration. For the reasons described below, the undersigned finds there is preponderant evidence sufficient to establish petitioner's flu vaccination was administered intramuscularly.

I. Procedural History

On December 21, 2017, petitioner filed a petition for compensation and medical records on December 29, 2017. See Exhibits 1-4, ECF No. 1, 6. Petitioner later filed an affidavit, additional medical records (ECF No. 10), and an amended Statement of Completion on April 16, 2018 (ECF No. 11) as ordered in a February 28, 2018 Scheduling Order. ECF No. 9.

Respondent filed a status report on October 15, 2018, indicating that additional outstanding medical records were identified to petitioner's counsel on that date. ECF No. 17. Petitioner filed additional records and another amended Statement of Completion on November 19, 2018. ECF No. 19 and 20. Petitioner later filed additional records on December 5, 2018. ECF No. 21.

On December 20, 2018, respondent filed a status report stating that respondent recommended that the parties explore informal resolution if petitioner could produce additional evidence that the vaccine was administered intramuscularly. ECF No. 23.

Petitioner was ordered to file additional evidence regarding the route of administration by January 22, 2019. ECF No. 24. On January 22, 2019, petitioner filed a status report stating that the vaccine administrator questioned the need for additional documentation, and that the record already noted the influenza vaccine was administered in petitioner's left deltoid, thus intramuscularly. ECF No. 25.

A call was held with the staff attorney managing this case on February 26, 2019. See ECF No. 26 (scheduling order describing call). Respondent's counsel provided context as to why the additional documentation was requested, stating that the particular vaccine administered to petitioner was manufactured by Sanofi and could be given either intramuscularly or intradermally. Petitioner was ordered to file any additional evidence regarding the route of administration by March 29, 2019.

On March 29, 2019, petitioner's counsel filed a status report stating that she had thus far been unable to discover additional information concerning the route of administration, and indicated that she would file any additional information available within 15 days. Petitioner was then ordered to file any additional evidence by April 15, 2019. ECF No. 28. Thereafter, the undersigned stated a fact ruling would issue as to the route of administration.

On April 16, 2019, petitioner filed additional information including Fluzone® Quadrivalent vaccine prescribing information for 2017-2018 (Ex. 10) and Fluzone® Quadrivalent prescribing information for 2018-2019 (Ex. 11).³

On May 7, 2019, a scheduling order noted that petitioner filed prescribing information for the 2017-2018 formula, and 2018-2019 formula. ECF No. 30. However, the vaccination record indicates that petitioner received the 2016-2017 vaccine formula. Petitioner was ordered to file any additional evidence by June 6, 2019.

On June 6, 2019, petitioner filed prescribing information for the 2016-2017 Fluzone® Quadrivalent vaccine formula. Ex. 12.

II. Factual History

A. Medical Records

Petitioner received a flu vaccination on January 5, 2017. Ex. 1 at 1, Ex. 3 at 1. At that time, petitioner was a 51 year old registered nurse. The vaccination record indicates that petitioner received a 2016/2017 Fluzone® Quadrivalent, vaccination, and the site of injection was indicated as the left deltoid. Ex. 1.

On January 26, 2017, petitioner presented to Jessica Wiggins N.P. complaining of left shoulder pain since receiving a flu vaccination. Ex. 2 at 9. Petitioner again complained of left shoulder pain on February 8, 2017, to Dr. Ruth Barnert. Ex. 2 at 6. Dr. Barnert indicated that petitioner “noted that the bandaid was high on her arm near the bursa.” *Id.*

B. Petitioner’s Affidavits and Additional Evidence

Petitioner submitted an affidavit in support of her claim on April 16, 2018. Ex. 6. In her affidavit, petitioner states that she is a registered nurse and received the flu vaccine at her place of employment on January 5, 2017. Petitioner also stated that she was sitting when the vaccine was administered “despite asking to stand which makes it easier to correctly place an intramuscular injection.” Ex. 6 at 1. Petitioner also stated that she developed severe pain over the next 24 hours, and “[b]ased on anatomical location, pain, & marked reduction in range of motion, it appeared that the vaccine had been delivered into the sub-deltoid bursa or within the joint space.” *Id.*

Petitioner also submitted the prescribing information for Fluzone® Quadrivalent from Sanofi Pasteur for the 2016-2017 formula. Ex. 12 at 1. The vaccine is described as a suspension for intramuscular injection, and that it is “[f]or intramuscular use only”. *Id.* at 1, 2. The prescribing information states that the preferred sites for intramuscular

³ Petitioner’s exhibits were filed out of time, were not accompanied by a Motion for Enlargement of Time, and no explanation as to why the material was late was provided to the Court.

injection is the deltoid muscle in an adult, and that the vaccine should not be administered intravenously, intradermally, or subcutaneously. Ex. 10 at 3. The prescribing information also states “Fluzone Quadrivalent (Influenza Vaccine) for intramuscular injection...” (*id.* at 11) and that “Fluzone Quadrivalent vaccine is a shot given into the muscle of the arm.” *Id.* at 21.

III. Findings of Fact

A petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding her claim. § 13(a)(1)(A). Under that standard, the existence of a fact must be shown to be “more probable than its nonexistence.” *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring).

There is a preponderance of evidence that petitioner received an intramuscular vaccination on January 5, 2017. Petitioner’s vaccine administration record affirmatively states the vaccine was injected into petitioner’s left deltoid. Ex. 1 at 1. The deltoid is defined as “triangular in outline, as the deltoid muscle.” *Dorland’s Illustrated Medical Dictionary* (32nd ed. 2012) at 484. Further, when petitioner first complained of shoulder pain, Dr. Barnert noted that she also stated the Band-Aid was high on petitioner’s arm near the bursa, which is consistent with the left deltoid injection site noted in the vaccine administration record. Ex. 2 at 6. In addition, petitioner is a nurse practitioner, and stated in her affidavit that she was sitting when the vaccine was administered, “despite asking to stand which makes it easier to correctly place an intramuscular injection.” Ex. 6 at 1.

The prescribing information for Fluzone® Quadrivalent from Sanofi Pasteur for the 2016-2017 formula is also helpful. Ex. 12 at 1. The prescribing information repeatedly describes the vaccine as suitable for intermuscular use. *Id.* at 1, 2, 11, 21. Further, it also affirmatively states the vaccine should not be administered intravenously, intradermally, or subcutaneously. Ex. 12 at 3.

Based upon the foregoing, in particular the vaccine administration record, petitioner’s affidavit, the prescribing information for the 2016-2017 Fluzone® Quadrivalent formula, and in light of no contradictory evidence, the undersigned finds there is preponderant evidence showing petitioner received an intramuscular flu vaccination on January 5, 2017.

IV. Conclusion

Accordingly, the following is ORDERED: **Respondent shall file, by no later than Friday, August 09, 2019, a status report indicating how he intends to proceed in this case.** At a minimum, the status report shall indicate whether he is willing to engage in tentative discussions regarding settlement or proffer or is opposed to negotiating at this time. In the event respondent wishes to file a Rule 4(c) report, he

may propose a date for filing it, but shall indicate his position on entering into negotiations regardless of whether he wishes to file a Rule 4(c) report.

IT IS SO ORDERED.

s/Nora Beth Dorsey

Nora Beth Dorsey
Chief Special Master